

REMARKS

Claims 2-7, 13-15 and 17-28 presently appear in this case. No claims have been allowed. The Official Action of June 30, 2006, has now been carefully studied.

Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for detecting the presence of one or more analytes in a solution, using proximity probes that include a binding moiety and a nucleic acid. The nucleic acid from one proximity probe is only capable of interaction with the nucleic acid from the other proximity probe when these are in close proximity, i.e., have bound to the analytes for which they are specific. Thus, detecting the degree of interaction between the nucleic acids is sufficient to detect the presence of one or more analytes in solution. This is known as a homogenous (or homogeneous) assay, as it does not require a solid phase. There are many advantages of homogenous assays over solid phase (or heterogeneous) assays.

The examiner states that claims 2-7, 20, and 23-27 are directed to an invention not patentably distinct from claims 1, 7, 21, 22 and 26 of commonly assigned U.S. patent 6,511,809. The examiner states that in order to determine whether the commonly assigned case qualifies as prior art under 35 USC 102(e), (f) or (g), the assignee can either show that the conflicting inventions were commonly owned at the time the invention in the present application was made or name the prior inventor of the conflicting subject matter.

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The present application was not commonly owned with the '809 patent at the time that the present invention was made. Accordingly, 35 USC 103(c) is not applicable.

The present application has an effective filing date of February 18, 2000, which is the date of filing of provisional application 60/183,371, from which the present application claims benefit. All of the present claims are supported by the disclosure of the provisional application. The '809 patent has an earliest effective filing date of June 13, 2000, which is subsequent to the February 18, 2000, effective filing date of the present application. Thus, the '809 patent is not available as a reference against the present application under 35 USC 102(e). Accordingly, the subject matter of the '809 patent can only be available as prior art against the present application if it is available under 35 USC 102(f) or (g).

Contrary to the examiner's statement, the claims of the present application are drawn to an invention that is patentably distinct from the claims of the '809 patent.

Claim 1 of the '809 patent is written broadly enough to cover the solid phase embodiment and the homogenous embodiment. Only the homogenous embodiment is being claimed in the present application. No claim of the '809 patent is specifically directed to the homogenous embodiment. The only embodiment specifically claimed in the dependent claims of the '809 patent is the solid phase embodiment.

35 USC 135(b)(1) states:

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A claim which is the same as, or for the same or substantially the same subject matter as, a claim of an issued patent may not be made in any application unless such a claim is made prior to one year from the date on which the patent was granted.

However, in the present situation, the claims of the present application are not "the same as, or for the same or substantially the same subject matter as" any of the claims of the '809 patent. As indicated above, claim 1 of the '809 patent is written broadly enough to be generic to the specific species (the homogenous species) claimed in the present application. The U.S. Court of Appeals for the Federal Circuit and its predecessor court, the U.S. Court of Customs and Patent Appeals, have made it quite clear that a claim to a species is not drawn to the same or substantially the same invention as a claim to a genus. See *In re Sasse*, 629 F.2d 675, 680, 207 U.S.P.Q. 107, 111 (CCPA 1980), where it states, "claims to a genus and claims to species within it are not claims to the same or substantially the same subject matter in the sense of §135(b) Section 135(b) is not applicable." In *In re McGrew*, 120 F.3d 1236, 1238, 43 USPQ2d 1632, 1634 (Fed. Cir. 1997), this language was quoted without disapproval, and the *McGrew* court indicated (120 F.3d at 1239; 43 USPQ2d at 1635) that this quote was part of the holding of *Sasse*. Accordingly, as claims to a genus and claims to species within it are not claims to the same or substantially the same subject matter in the sense of §135(b), the claims of the present application are not directed to the same or

substantially the same subject matter as the claims of the '809 patent and therefore there is no interfering subject matter between those claims.

Nevertheless, to answer the examiner's inquiry as to who is the prior inventor of subject matter that is allegedly conflicting, an investigation has established that the present inventors invented the homogenous embodiment prior to the date that the '809 inventors invented the homogenous embodiment (disclosed but not specifically claimed therein). However, the '809 inventors invented the solid phase embodiment prior to the date that the present inventors invented the homogenous embodiment. However, even if the solid phase embodiment of the '809 patent is available as a reference against the present claims under 35 USC 102(g)/103, the present claims are only unpatentable if they are not patentably distinct from the solid phase embodiment previously invented by the '809 inventors. In other words, if all of the present claims, which only read on the homogenous embodiment, are patentably distinct from the solid phase embodiment, then the present claims are patentable.

It has already been established on this record that claims to the homogenous embodiment are patentable over a prior publication of the solid phase embodiment by Landegren (WO 97/00446), in light of applicants' arguments and declaration under 37 CFR 1.132. The examiner has already concluded that the declaration and arguments were sufficient to overcome the previous rejection over Landegren (which

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discloses the same solid phase embodiment as was later invented by the '809 inventors) in view of Ebersole. Accordingly, it is again requested that the examiner confirm for the record that all of the present claims are patentably distinct from the prior invention of the solid phase embodiment by the '809 inventors, just as they were held to be patentably distinct from the prior publication of the solid phase embodiment by Landegren.

Since the filing of applicants' amendment of March 28, 2005, the Federal Circuit issued its decision in *University of California v. University of Iowa Research Foundation*, 455 F.3d 1371, 79 USPQ2d 1687 (Fed. Cir. 2006). This decision has been interpreted as possibly changing the way courts look at small changes made to the claims of an application between the language of the claims as they existed within a year of the issuance of a patent with allegedly interfering subject matter and the language of the claims as amended after the one year deadline set by 35 USC 135(b). While applicants firmly believe and urge that there is no interfering subject matter between the present application and the '809 patent, for the reasons indicated above, nevertheless, out of an abundance of caution, new claim 28 is being presented herein, which is identical in language to the way claim 25 read prior to the one year deadline following the issuance of the '809 patent. The changes made to claim 25 in applicants' amendment of March 28, 2005, were only made for emphasis, but none of the changes were material and none were

necessary in order to define over the Landegren and Ebersole references that were used in a rejection under 35 USC 103 prior to that amendment. There is no material difference in scope as between present claim 28 (which is the same as present claim 25 prior to the amendment of March 28, 2005) and present claim 25 (as amended on March 28, 2005). For example, the previous language, i.e., the language of new claim 28, "the proximity probes comprise" has the same scope as the amended language (i.e., the language of present claim 25), "each proximity probe comprises." The change was merely made for clarity and emphasis but not to change the scope of the claim. There was no limitation added, let alone a material limitation.

In applicants' amendment of March 28, 2005, applicants stated:

Accordingly, Ebersole actually teaches away from the present invention and therefore simply cannot be combined with the disclosures and teachings of the applied Landegren reference to lead one of ordinary skill in the art to the present invention. This is especially true because claim 25 is amended to recite that each (or in other words, all) proximity probe comprises nucleic acids acting as a reactive functionality coupled to the binding moiety.

The last sentence of this quote was not intended to imply that there was a substantive or otherwise material change made to the claim. The language of claim 28 (i.e., claim 25 prior to the amendment of March 28, 2005) still requires that the proximity probes all comprise nucleic acids acting as a

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reactive functionality coupled to the binding moiety.
However, even if claim 28 were interpreted differently, the difference is not necessary to define over the prior art in view of the declaration under 37 CFR 1.132 submitted with the amendment of March 28, 2005, which establishes unexpected results that are not made predictable by Ebersole. Accordingly, entry and allowance of new claim 28 (which is old claim 25), is respectfully urged.

As no rejections are applicable under 35 USC 102(e), (f) or (g), either for anticipation or with 35 USC 103 for obviousness, and as there are no other rejections of record, the present application should now be in condition for allowance. Prompt consideration of this response and allowance of the present application are therefore earnestly solicited.

Respectfully submitted,

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